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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,272	04/20/2004	Zhaoxi Ke	CL001313-DIV	2775

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/827,272	KE, ZHAOXI	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 24-38* is/are pending in the application.

4a) Of the above claim(s) *1,2,37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20040420, 20040917*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of U.S. Application Serial Number 10/067,977.

Claims 4-23 have been canceled.

New claims 24-38 have been added.

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

Election/Restrictions

1. Applicant's election with traverse of group II, claim 3, which is drawn to antibodies, in the reply filed on November 2, 2006 is acknowledged. The traversal is on the ground(s) that a search of the antibodies of Group II would necessitate a search of the polypeptide of Group I and therefore combining the inventions would not constitute a serious burden. This is not found persuasive because the Groups are separately classified and must be searched separately both in the patent and non-patent literature. Further, knowledge of an antibody can exist in the art without knowledge or disclosure of its cognate antigen.

The requirement is still deemed proper and is therefore made FINAL.

2. It is noted that **new claims 24-36 are drawn to the invention of Group II** and therefore will be examined in this Office Action along with claim 3.

3. **Claims 1, 2, 37 and 38 are withdrawn** from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 2, 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 24, 26, 28, 30, 32, 34, and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to antibodies specific for a polypeptide that "comprises SEQ ID NO: 2." However, the term "comprising" is an open term that is inclusive of larger polypeptides that contain SEQ ID NO: 2, such as a fusion protein, and the claim is not limited to antibodies that are specific for SEQ ID NO: 2 but includes in scope antibodies that bind to any appended amino acid sequences, such as a fusion partner. The instant specification, however, teaches only antibodies to SEQ ID NO: 2, not antibodies reactive with such a fusion partner.

Therefore, only antibodies that are specific for the amino acid sequence instantly disclosed as SEQ ID NO: 2 meet the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 3 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster et al (Mol. Cel. Biol. [1993] 13(4):2031-2040; U on form PTO-892) in view of Campbell (Monoclonal Antibody Technology [1985] pages 1-32; V on form PTO-892).

The claims are broadly drawn to an antibody that specifically binds to a polypeptide consisting of SEQ ID NO: 2. The claims are to be given their broadest reasonable interpretation and the claims are to be read in light of the specification. Lines 17-22 of page 24 in the instant specification recite:

> "As used herein, an antibody selectively binds a target peptide when it binds the target peptide and does not significantly bind to unrelated proteins. An antibody is still considered to selectively bind a peptide even if it also binds to other proteins that are not substantially homologous with the target peptide so long as such proteins share homology with a fragment or domain of the peptide target of the antibody. In this case, it would be understood that antibody binding to the peptide is still selective despite some degree of cross-reactivity."

Webster teaches the rat *sgk* gene product, a serum and glucocorticoid-regulated kinase (see entire document, Figure 1 in particular). The SGK protein taught by Webster is 90.5% identical to instant SEQ ID NO: 2. furthermore, the instant specification identifies the SGK protein of Webster as being related to the instant protein of SEQ ID NO: 2 at page 5, lines 5-13 for example.

Webster does not teach antibodies to the rat SGK protein; however, methods of making monoclonal antibodies to a particular protein are well known and routinely practiced by those in the art, as evidenced at page 24, lines 28-30, of the instant specification.

Campbell teaches that "[i]t is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)" (page 29, section "Basic research" in particular). Campbell teaches that use of monoclonal antibodies allows one to select for a specific determinant and reduces the potential for cross-reactivity, allowing one to select the amount of affinity for the antigen (pages 5-7 in particular). Campbell also teaches at page 13 that monoclonal antibodies serve as a standard reagent. The practitioner does not need to repeatedly characterize the nature of the antibody, as one needs to do for the polyclonal antibodies obtained from different immunized animals or from different 'bleeds' from a particular animal.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make monoclonal antibodies specific for SGK. One would have been motivated, with a reasonable expectation of success, to generate mAbs to the peptides based on the fact that it is a conventional practice in the art and would have been further motivated to further establish the relationship of the novel protein to the serum and glucocorticoid-regulated kinase family.

6. Claims 3, 24-30, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster et al (Mol. Cel. Biol. [1993] 13(4):2031-2040; U on form PTO-892) in view of Campbell (Monoclonal Antibody Technology [1985] pages 1-32; V on form PTO-892) and Harlow et al. (Antibodies: A Laboratory Manual. [1988] pages 72-77, 92-97, 126-135, 141-157, 271, 274-275, 321-323 and 626-631; W on form PTO-892).

Webster and Campbell have been discussed supra.

The combined references do not teach antibody fragments or coupling to a detectable substance.

Harlow teaches that any substance that can elicit a humoral response can be used to prepare mAbs and that mAbs are powerful reagents for the testing for the presence of a desired epitope. Harlow teaches methods for immunizing animals for the production of polyclonal and monoclonal antibodies (pages 72-77, 92-97, 128-135 and 141-157 in particular) as well as the types of antigens to which such antibodies can be made including proteins, peptides, and carbohydrates (any of which could qualify as a ligand, depending on the receptor)(pages 153-154 in particular). Harlow further teaches that because antibodies may recognize small determinants they may be cross-reactive with similar epitopes on other molecules (page 24, last paragraph in particular) and that epitopes may be formed by linear epitopes within an amino acid sequence or to epitopes which are formed by determinants from different parts of a molecule which are brought together due to conformation of said molecule (page 25, first section in particular). Harlow further teaches the manufacture of Fab and $F(ab')_2$ fragments of monoclonal antibodies (pages 628-631 in particular). Harlow also teaches the conventional practice of labeling antibodies with a detectable substance (pages 321-323 in particular).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine these references to produce monoclonal antibodies to the SGK protein taught by Webster. One would have been further motivated, with a reasonable expectation of success, to combine these references in order to generate monoclonal antibodies to SGK by Harlow's teaching that hybridomas which produce mAbs provide a limitless supply of antibodies which is desirable because even large supplies of antisera (polyclonal) will eventually run out (pages 141-142, section titled "Monoclonal antibodies are powerful immunochemical tools"). One would have been further motivated to generate antibody fragments by the teachings of Harlow that the use of intact antibody molecules in some techniques introduces certain problems, such as capping and internalization of the antigen (page 626 in particular). one would have been motivated to attach a detectable substance to an antibody by Harlow's teaching that a wide range of immunological techniques depend upon the use of labeled antibodies (page 321 in particular).

7. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster et al (Mol. Cel. Biol. [1993] 13(4):2031-2040; U on form PTO-892) in view of Campbell (Monoclonal Antibody Technology [1985] pages 1-32; V on form PTO-892) and Harlow et al. (Antibodies: A Laboratory Manual. [1988] pages 72-77, 92-97, 128-135, 141-157, 271, 274-275, 321-323 and 626-631; W on form PTO-892) as applied to claims 3 and 24-26 above, and further in view of U.S. Patent No. 5,643,740 to Billing et al (A on form PTO-892).

Webster, Campbell and Harlow have been discussed supra.

The combined references do not specifically disclose a pharmaceutically acceptable carrier.

Harlow further teaches that monoclonal antibodies can be produces in ascites fluid in higher titers than possible in tissue culture (pages 271 and 274-275 in particular).

The '740 patent discloses the administration of murine monoclonal antibodies into a human subject in murine ascites fluid (columns 13 and 14 in particular). Accordingly, ascites fluid is a pharmaceutically acceptable carrier.

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to produce monoclonal antibodies to the SGK protein of Webster using ascites fluid as taught by Harlow. One would have been motivated to combine the teachings with a reasonable expectation of success by the teaching of Harlow that high-titered solutions of a monoclonal antibody can be produced using this technique.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
January 20, 2007

David A. Saunders

DAVID A. SAUNDERS
PRIMARY EXAMINER